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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,472	07/16/2002	Thomas Brevig	1501-1010	3394

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,472

Applicant(s)

BREVIG ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/24/02 ; 5/16/02
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-5) in the reply filed on 6 July 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims **6-14** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6 July 2004.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 1, 2, 4, and 7 contain labels which are not in the Specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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3. The drawings are objected to because Figures 3, 8, 9, 10, and 14 have multiple parts and should be labeled (for instance, "3A, 3B, 3C"). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: typo "i e" (pp. 3 line 11); "comprising" (pp. 11 line 12); bicarbonate) (pp. 11 line 28).

Appropriate correction is required.

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code ("soriag@aol.com"; pp. 26 line 14). See MPEP §608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 5 provides for the use of transplantation material, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,411,883 (Boss *et al.*) 2 May 1995.
10. US '883 teaches a preparation porcine neuron progenitor cells isolated from the ventral mesencephalon. Said cells were isolated via mechanical dissociation and enzymatic treatment with DNAase thus meeting the limitations of claims 1-4 (Col. 4 lines 1-15; Col. 5 lines 15-40; Col. 8-9). US '883 also teaches the transplantation of said cells into a rat model of Parkinson's disease thus constituting a "pharmaceutical preparation" and meeting the limitations of claim 5 (Col. 14-15; Claims 1 & 4).
11. It has been established by the courts that a product inherently possesses characteristics of that product regardless of its method of manufacture (*e.g.* porcine embryonic or fetal tissue essentially free of macrophages and/or microglial cells). See, *e.g.*, *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

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“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved”. *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

12. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

13. The Examiner notes that no temporal limitations are present such as a gestation week or embryonic day. Nor are any anatomical restrictions present other than neural (Relating to any structure composed of nerve cells or their processes, or that on further development will evolve into nerve cells; see Stedman's Medical Dictionary) in the instant claims. As such, any dissociated (by any means) porcine (of, relating to, or derived from a pig, see Dictionary.com) embryonic or fetal tissue essentially free of macrophages and/or microglia meets the limitations of claim 1. Since US '883 is silent on the prescience of any macrophages and/or microglia in the neuron progenitor cell culture it is taken to be essentially free of such cells.

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14. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacoby *et al.* (November 1997) "Fetal Pig Neural cells as a Restorative Therapy for Neurodegenerative Disease." Artificial Organs 21(11): 1192-1198.
15. Jacoby *et al.* teaches fetal pig neural cells derived from fetal striatal cells taken from the lateral ganglionic eminence (LGE) thus meeting the limitations of claims 1 and 4 (pp. 1193). Jacoby *et al.* teaches that said fetal pig neural cells were obtained via physical dissection followed by trituration and treatment with trypsin, a protease, and DNAase, a deoxyribonuclease, thus meeting the limitations of claims 1-3 (pp. 1193). Jacoby *et al.* also teaches the transplantation of said cells into nude rat model thus constituting a "pharmaceutical preparation" and meeting the limitations of claim 5 (pp. 1194; Figure 1).
16. It has been established by the courts that a product inherently possesses characteristics of that product regardless of its method of manufacture (e.g. porcine embryonic or fetal tissue essentially free of macrophages and/or microglial cells). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).
17. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in

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which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

18. The Examiner notes that no temporal limitations are present such as a gestation week or embryonic day. Nor are any anatomical restrictions present other than neural (Relating to any structure composed of nerve cells or their processes, or that on further development will evolve into nerve cells; see Stedman's Medical Dictionary) in the instant claims. As such, any dissociated (by any means) porcine (of, relating to, or derived from a pig, see Dictionary.com) embryonic or fetal tissue essentially free of macrophages and/or microglia meets the limitations of claim 1. Since Jacoby *et al.* is silent on the presence of any macrophages and/or microglia in the fetal pig neural cells there are taken to be essentially free of such cells.

19. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Talbot *et al.* (July 1993) "Culturing the Epiblast Cells of the Pig Blastocyst." In Vitro Cell Devl Biol. 29A(7): 543-554.

20. Talbot *et al.* teaches a distinct cell culture of neural crest cells derived from pig blastocytes thus meeting the limitations of claims 1 and 4 (pp. 543; Table 1). Talbot *et al.* teaches that said neural crest cell culture was obtained via physical dissection and treatment with trypsin, a protease thus meeting the limitations of claims 1-3 (pp. 544).

21. It has been established by the courts that a product inherently possesses characteristics of that product regardless of its method of manufacture (e.g. porcine embryonic or fetal tissue

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essentially free of macrophages and/or microglial cells). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved”. *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

22. Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

23. The Examiner notes that no temporal limitations are present such as a gestation week or embryonic day. Nor are any anatomical restrictions present other than neural (Relating to any structure composed of nerve cells or their processes, or that on further development will evolve into nerve cells; see Stedman's Medical Dictionary) in the instant claims. As such, any dissociated (by any means) porcine (of, relating to, or derived from a pig, see Dictionary.com) embryonic or fetal tissue essentially free of macrophages and/or microglia meets the limitations of claim 1. Since Talbot *et al.* is silent on the presence of any macrophages and/or microglia in the cell culture it is taken to be essentially free of such cells.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

August 30, 2004



ELIZABETH KEMMERER
PRIMARY EXAMINER